

Check out the SPL Working Group WIKI @:

<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

Kits (aka “Most of the Kits we’ve been getting in have been strangely coded”)

Validation procedures for Release 4 were written to catch many of the previous KIT errors.

The data (Product Data Element section) is intended more for downstream use (EHR) than human readability. The person using this SPL is likely to have read the content of labeling before they ever get to the Data Elements.

Some KIT pointers:

General Principles:

1. When you are describing a KIT, the first level packaging should always be 1 KIT and some kind of container (1 KIT in 1 CARTON)
 - First level of packaging is the overall KIT level
 - Even for a single blisterpack with multiple dosing strengths... first level would be 1 KIT in 1 BLISTERPACK
 - Always choose KIT as the Dosage Form
2. A KIT contains 1 or more part(s).
 - You can have as many parts as are applicable to your product
 - If you have a drug/device or a drug/food combination or a drug/cosmetic combination, you do not include the device or food as a part
 - When you are adding the packaging for the components, include in the quantity of parts – you can identify the # of tablets in each part. No need to enter data redundantly.
 - You should have a marketing category for each part. If you don’t have a marketing category, probably you shouldn’t be including the part. Exception – diluents approved as a part of the kit will get the marketing category as the other part.
 - There should be a marketing category for each part, as well as for the kit

3. When you are coding kits, make sure that the NDC product code for the KIT is different than any of the NDC codes for the parts. Previous duplication will no longer be permitted.
 - If you don't have the NDC code for the part level, you also should not have the NDC codes lingering in the background
 - You can have a different NDC labeler code from the KIT labeler code only in KITS.
 - Repackers and relabelers should either use the source NDC product code or include the name of the actual manufacturing site in their listing SPL document.
4. When you are listing convenience kits that include a medical device requiring SPL – you'll use the medical device marketing category.
 - Some convenience kits contain all the drug components for a specific medical procedure.
 - Marketing Categories: Exempt Device, Humanitarian Device, Pre-Market Notification (don't use this for drugs that are not yet marketed), Pre-Approval Notification are only used with Medical Device convenience kits.
 - Include all the content of labeling for each of the drug components. While this may seem like a lot of content of labeling to add, it's required by DRLS.
 - When you are describing a medical device such as a syringe, you can include the amount of material pre-filled in the syringe.
 - The only situation where you can have only inactive ingredients is in a KIT (some divisions consider swabs w/ alcohol an active ingredient, others consider it a inactive ingredient)
 - Q: Kit with active, and diluent – Kit NDC code, Active NDC code, and Diluent NDC ... parts don't HAVE to have NDC codes at all.

Note: When you receive a Word document, it's usually the FDA providing special instructions. Usually the Word document is sent after the receipt/acknowledgement.

Note for Repackers and Relabelers:

Repackers and relabelers should either use the source NDC product code or include the name of the actual manufacturing site in their listing SPL document. Additionally, if an SPL is downloaded from DailyMed, and then re-used by another organization, remember to replace the downloaded setid.

“Dec 14 discussion with DRLS ”

Scenarios attached to these minutes

Issue 1: Business Operations in Drug Listing

The team strongly recommended that the FDA provide definitions (more formal than the notes next to for each of the following SPL Acceptable Terms for Business Operations:

Analysis – a lab that works with a manufacturer to put a final drug out on the market. If a lab is simply doing research

API Manufacture – definition is in 207

Import – the person or facility that a foreign establishment uses to put a product on the US

Manufacture – definition is in 207

Outsourcing Human Drug Compounding (This one is new and many folks need clarification as to what this means.) – (compounding pharmacy) – prepare compounding drugs to be outsourced to hospitals, etc.

Recovery - Drug Salvagers, definition in 207

Relabel – third company that is putting a product out under a different name

Repack– third company that is putting a product out under a different name

Some specific examples for Repack and Relabel would be especially beneficial. The Team is concerned that firms are interpreting these business operations differently, and this will result in failing SPL files.

Issue 2: DailyMed Posting/NDC Directory Update

Q: What is the standard time frame for a successfully validated SPL to appear on DailyMed and appear in the NDC Directory? Industry has had many different experiences with these postings...sometimes they are posted within a couple days and sometimes it takes weeks.

Some variability may arise as a result of the more intensive questions before a listing goes to the NDC directory.

“Update on UDI and SPL Device harmonization”

Sounds like some activity around SPL and devices regulated by CDRH will start in January 2010. First step was to see which UDI elements matched to SPL elements. CDRH will be looking for pilot participants in 2010.

FYIs:

- New eCards (all at <http://spl-work-group.wikispaces.com/SPL+eCards+-+Quick+Reference>)
Intended as Quick References, the information for each ER/DL scenario is presented in flowchart format.
- SPL Roadmap (http://spl-work-group.wikispaces.com/file/view/roadmap_creating_and_submitting_spl_R4.pdf)
- Pragmatics Lite Validator information (<http://spl-work-group.wikispaces.com/Common+Technical+Errors+with+SPL>)

As of December 21, 2009 there are 6029 SPL on DailyMed

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Drug Product Scenarios—to clarify assignment of Business Operations in Drug Listing

Scenario 1

Activity	<i>Business Operation identified in Drug Listing</i>
Perrigo manufactures drug product for GSK. Perrigo ships drug product to GSK for final packaging.	Perrigo: Manufacture
GSK packages drug product for final distribution.	GSK: Manufacture should be Repacker
GSK sells drug product under GSK name and NDC number.	GSK: Identified as Labeler

Scenario 2

Activity	<i>Business Operation identified in Drug Listing</i>
Company A manufactures drug product in 100 count bottles.	Company A: Manufacture
Company B purchases 100 count bottles and repackages drug product in 25 count bottles under company B name and NDC number.	Company B: Repackager

Scenario 3

Activity	<i>Business Operation identified in Drug Listing</i>
-Hospira Australia manufactures drug product, including final packaging under Hospira name and NDC number on risk prior to FDA approval. -Unapproved packaged/labeled product is shipped to Free Trade Zone at Hospira Kansas.	Hospira Australia: Manufacture
Hospira Kansas repackages approved product with new labeling (due to FDA required changes) prior to distribution.	Hospira Kansas: Manufacture (or Repackage?) if packaging is not being changed, then they are labelers

Scenario 4

Activity	<i>Business Operation identified in Drug Listing</i>
Lilly site #1 manufactures and tests API.	Lilly Site #1: API Manufacture and Analysis
Lilly site #2 manufactures bulk drug product (eg bulk capsules) and tests the drug product. Bulk capsules are sent to either another Lilly site...or a third party contract manufacturer to do the packaging and labeling (eg blistering and labeling).	Lilly site #2: Manufacture and Analysis
Lilly site #3 or a third party manufacturer performs final packaging (eg packaging in blisters) and labeling of the product. Ships product to distribution center.	Lilly site #3 or Contract Manufacturer: Manufacture ... Distributors

One establishment doing everything – you can use Manufacturer alone (not add Labeler, Analysis)

